UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,296	07/12/99	SEIDEL C	P564-9016

HM22/0214

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	5

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trade

Office Action Summary	Application No.	Applicant(s)	
	09/351,296	SEIDEL ET AL.	
	Examiner	Art Unit	
	Mary Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-48* is/are rejected.

7)☒ Claim(s) *49* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Applicant's arguments filed 12/05/00 have been fully considered but they are not completely persuasive. Any non-reiterated rejections have been withdrawn.

Claims 29-49 are pending in this application. Claims 11-28 have been canceled, and claims 29-49 are newly added.

Claim Rejections - 35 USC § 112

Claims 39-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 39, the peptide characteristics of step (a) are described as (1), (2) and (3), however, the claims depending from claim 39 (40, 41 and 44) refer to those peptide characteristics as (a), (b) and (c), which is incorrect.

Step (b) of the methods of claims 39 and 45 do not set forth that the antibody detected or not detected is from the sample. It would appear both the preamble and the last sentence of the claims should be amended to recite something to the effect of: "... detecting the presence or absence of an antibody against hepatitis C virus in a sample..." and "in said sample."

The metes and bounds of claim 45 are unclear. Step (a) sets forth that 2 peptides are to be used, P1 and P2, yet only sets forth characteristics of one peptide, and does not identify whether those characteristics belong to the designation P1 or P2. No characteristics of the second antigen are set forth such that one of skill in the art would recognize what Applicant intends to use in the claimed method. This confusion continues in to claim 47, as it is entirely unclear which peptide is intended to be bound to a solid phase.

Steps (e) and/or (f) of claim 48 do not set forth that the antibody detected or not detected is from the sample. It would appear both the preamble and either step (e) or (f) or both should be amended to recite something to the effect of: "... detecting the presence or absence of an antibody against hepatitis C virus in a sample..." and "in said sample."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 48 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,935,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant methods are limited to detecting HCV specific antibodies in a sample, wherein the patent discloses a genus of antigens to be detected. Claim 8 of the patent sets forth detecting HCV-specific antibodies. Each method uses at least 3 differing antigens to type the antibodies present in a sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 29-47 are rejected under 35 U.S.C. 102(e) as being anticipated by DeLeys et al. (USP 5,891,640).

Claims 29-38 are drawn to peptides of 6-22 amino acids (or 9-22 amino acids) from one of sequences 11-16. The peptides optionally have a spacer region, and are optionally bound to a solid phase binding group, or marker group. Claims 39-47 are drawn to methods of diagnosing the presence or absence of antibodies to HCV by using those peptides in an immunoassay.

DeLeys et al. (USP 5,891,640 having a 102(e) date of 22 November 1993) discloses SEQ ID NO: 356, 357, 362 and 363, each of which is a 9 amino acid peptide, having 100% identity to SEQ ID NO: 11 (See figure 7b-2 of the patent). SEQ ID NO: 356 of the '640 patent is identical to residues 1-9 of SEQ ID NO: 11 of the instant invention. SEQ ID NO: 357 of the '640 patent is identical to residues 4-12 of SEQ ID NO: 11 of the instant invention. SEQ ID NO: 362 of the '640 patent is identical to residues 3-11 of SEQ ID NO: 11 of the instant invention. SEQ ID NO: 363 of the '640 patent is identical to residues 4-12 of SEQ ID NO: 11 of the instant invention. Further peptides anticipating a peptide having 6-22 amino acids of SEQ ID NO: 11 are also set forth in Figure 7b-2, including:

Peptide of Patent	identity to SEQ: 11 (residues)
TASRQAEVI	1-9
ASRQAEVIA	2-10
QAEVIAPAV	5-13
AEVIAPAVQ	6-14
EVIAPAVQT	7-15
VIAPAVQTN	8-16
IAPAVQTNW	9-17
APAVQTNWQ	10-18

DeLeys et al. disclose that the peptide can be coupled to an immunologically inactive linker, and then a marker group; or a solid phase binding group at column 5 lines 19-64. The inactive linker is represented by "Y" in that disclosure, and the marker group/ solid phase binding activities are performed by Biotin, represented as "B" in that disclosure. The methods for immunoassay using the biotinylated peptides is set forth at columns 16-19. These peptides are able to bind antibodies in a sample specific for HCV. (Fig 7b-3) DeLeys et al. also disclose using more than one HCV specific peptide in the immunoassays, as required for instant claim 45-47. Therefore, the disclosure of DeLeys et al. meets the limitations of the pending claims.

Claims 29-47 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLeys et al. (WO 93/18054 16 November 1993; WO Equivalent of Patent 5,891,640 to DeLeys).

DeLeys et al. (WO 93/18054 16 November 1993; WO Equivalent of Patent 5,891,640 to DeLeys) discloses 9 amino acid peptides, having 100% identity to SEQ ID NO: 11 (See figure 7b-2 of the patent and table below). This meets the limitation of a peptide 6-22 amino acids of SEQ ID NO: 11, and 9-22 amino acids of SEQ ID NO: 11:

Peptide of Patent	identity to SEQ: 11 (residues)
TASRQAEVI	1-9
ASRQAEVIA	2-10
SRQAEVIAP	3-11
RQAEVIAPA	4-12
QAEVIAPAV	5-13
AEVIAPAVQ	6-14
EVIAPAVQT	7-15
VIAPAVQTN	8-16
IAPAVQTNW	9-17
APAVQTNWQ	10-18

DeLeys et al. disclose that the peptide can be coupled to an immunologically inactive linker, and then a marker group; or a solid phase binding group. The inactive linker is represented by "Y" in that disclosure, and the marker group/ solid phase binding activities are performed by Biotin, represented as "B" in that disclosure. A myriad of methods for immunoassay using the biotinylated peptides are set forth throughout the disclosure. These peptides are able to bind antibodies present in a sample specific for HCV. (Fig 7b-3) DeLeys et al. also disclose using more than one HCV specific peptide in the immunoassays, as required for instant claim 45-47. Therefore, the disclosure of DeLeys et al. meets the limitations of the pending claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

mkz
February 1, 2001

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